Chlamydia/Gonorrhea Screening at Community Based Organizations

Division of Disease Prevention:
STD Surveillance, Operations and Data Administration (SODA)

Virginia Department of Health

109 Governor Street
Richmond, VA 23219

Office: 804-864-7964

Fax: 804-864-7970

VDH VIRGINIA DEPARTMENT OF HEALTH

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Revision History

Version	Date	Description of Changes
1	6/9/16	Original document
1.1	9/7/16	Added Conflict of Interest statement

Purpose

This document is written for non-laboratory personnel responsible for the collection and transport of urine and rectal swab specimens for chlamydia/gonorrhea (CT/GC) screening. Specimen analysis, outcome, diagnosis, and therapeutic decisions are highly sensitive to deviations in collection method, container, transportation, and storage; therefore, all personnel in contact with urine specimens must ensure the proper collection, preparation, and transportation of specimens to the laboratory.

Conflict of Interest

Agencies should not provide testing to persons who are employed by the agency providing testing. Additionally, if the client to be tested is a friend or associate of the test counselor, and either the client or the test counselor is uncomfortable with the situation, the test counselor shall immediately locate another staff person to provide services to the client. The counselor should verify that that the client is comfortable with the test counselor performing the counseling and knowing their test result. Test counselors should not provide chlamydia or gonorrhea testing to their co-workers. Agencies should assist their staff in locating another test site for services.

Collection Site

Collection sites must have all necessary personnel, supplies, and facilities to provide for specimen collection and storage until the specimen is ready for transportation. A collection site must have:

1. Provisions for client privacy while he/she provides a urine or swab specimen. The following facilities provide adequate privacy for collections:
   - An enclosed stall in a multi-stall restroom
   - A single person restroom
   - A partitioned area that allows for individual privacy
2. A means for washing hands.
3. A suitable clean surface, for the collector to use as a work area.
4. A secure temporary storage area for maintaining specimens until transferred for collection by the applicable laboratory. Procedures must provide for the secure handling and storage of specimens. Specimens must NOT be exposed to extreme temperatures as it may affect the test results.
5. Procedures or restrictions to prevent:
   - Unauthorized access to the collection materials/supplies;
   - Unauthorized access to collection site records; and
   - Access to items that could be used to adulterate, substitute, or dilute the specimen.

Supply Orders

To order collection kits or lab forms, send the following information to the VDH contact listed below: organization name, your name, contact information, shipping address, and quantity of kits needed.

Order in advance before you run out of supplies, as it can take up to 10 to 14 days to receive supplies. To avoid having test kits expire, order a reasonable quantity, monitor expiration dates, and rotate stock of test kits often by practicing “first in, first out”. Supply orders should be based on an approximate supply for three months.

Once you receive delivery, verify the package contents and authorize the packing slip with your signature and the date. Scan/email or fax the authorized slip to the VDH Central Office with "Attention: Emily Cothran" clearly legible on the document.

Emily Cothran
Virginia Department of Health
Email: emily.cothran@vdh.virginia.gov
Fax: (804) 864-7970

Specimen Transport and Storage

As soon as the specimen is collected and the container appropriately labelled, the specimen container must be placed in an individual biohazard specimen bag. Ensure the lid is tightened on the transport tube to prevent spillage. The appropriate requisition form must be completed and placed in the side pouch separate from the specimen container. The requisition should not be placed in the same part of the individual biohazard specimen bag as the specimen.

Urine Specimens – processed by DCLS

Research evidence indicates the performance of male first catch urine samples is equivalent to, and in some situations superior to, urethral swabs. In men, the use of urine samples is highly acceptable and may improve the likelihood of uptake of routine screening.

First catch urine from women, while acceptable for screening, might detect up to 10% fewer infections when compared with vaginal and endocervical swab samples (Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae - MMWR / March 14, 2014 / Vol. 63 / No. 2). Self-collected vaginal test kits are available in lieu of urine, if requested.

Eligibility

Clients who provide urine samples for a CT/GC screening must:

- Be over 15 years old;
- Have not urinated in the past hour; and
- Have not had a positive lab test or been treated for CT or GC in past 4 weeks.

Collection Procedures and Handling

The laboratory will provide kits which include disposable transfer pipette and sterile specimen transport tubes. Sterile collection cups do not come with the kit, and must be purchased independently from Colonial Scientific (state contract) or another medical supplier. The following procedures must be carefully followed to ensure the proper collection and handling of a urine specimen:

- Direct the patient to provide first-catch urine (20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives.

  - First-catch urine is concentrated, which results in a higher likelihood of pathogen identification in an infected individual, thus yielding the best test sensitivity. Collection of a large volume of urine can reduce the test sensitivity.
  - Female patients should not cleanse the labial area prior to providing a urine specimen.
- Remove the cap and transfer 2 mL of urine using the disposable pipette provided in the test kit from the collection cup into the urine specimen transport tube. The fluid level must be between the black fill lines on the urine specimen transport tube label (Figure 1).
- Do not pour the clear liquid out prior to transferring the urine sample from the cup to the tube. The clear liquid is a preservative that provides the specimen with more stability for longer storage.
- Urine samples must be transferred from the collection cup to the urine specimen transport tube within 24 hours of collection.
- Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen, which can be kept at room temperature or in the refrigerator.
- Affix a white sticker label to the specimen collection tube with the following information:
  - Name (must be an exact match to the lab requisition form)
  - Date of birth
  - Date of specimen collection
  - Specimen type (urine)
  - Additional patient identifier, if available (chart number, client ID, etc.)
  - Do not cover the expiration date on the specimen collection tube with the white sticker label.
- Complete all fields of the Blood and Body Fluid form (including race/ethnicity) and place in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.

Figure 1: Urine Specimen Transfer

Maintain the integrity of the processed urine specimen with proper and secure storage for transportation and handling. Processed urine specimens must be kept at room temperature or refrigerated until on-site courier collection or transportation to the off-site facility for evening courier collection by the applicable laboratory. Processed urine specimens must not be frozen as it compromises the viability of the infecting agent.

For off-site courier collection: Processed urine specimens must be delivered to the off-site facility for evening courier collection. Specimens must be delivered timely and in accordance with the pre-determined collection schedule to ensure viable specimens for analysis. The CBO is responsible for exercising and maintaining proper communication with the off-site facility to discuss changes in courier availability, as necessary (e.g. in events of inclement weather).

Submission Issues that Delay Testing or Prompt Rejections from DCLS

Specimens may be rejected for the following reasons:

1. Incorrect volume in the processed urine specimen tube: the volume of samples must be between the fill lines to be tested.
2. Incorrect or missing specimen source on the processed urine specimen tube and/or the Blood and Body Fluid form.
3. Missing or inconsistent patient name; patient name on the specimen label and both sides of the Blood and Body Fluid form must be consistent. Use printed specimen tube labels whenever possible and put identical labels on all three locations (front/back of the form and specimen tube).
4. Missing or inconsistent collection date listed on the processed urine specimen tube label and/or the Blood and Body Fluid form.
5. Missing indication of "requested test" on the Blood and Body Fluid form.
6. Use of whiteout on processed urine specimen tube label or Blood and Body Fluid form. Mistakes should be corrected by marking a line and rewriting the correct information above or beside it. Any evidence of whiteout will prompt rejection.
7. Missing submitter location on the Blood and Body Fluid form. No results can be provided without indication of the location that submitted the specimen.
8. Missing or broken foil top of processed urine specimen tube; the foil must be intact to preserve the sample integrity.

DCLS Courier

DCLS laboratory courier service will not be available on the following holidays:

New Year's Day	Memorial Day	Veteran's Day
Lee-Jackson Day	Independence Day	Thanksgiving
Martin Luther King, Jr. Day	Labor Day	Christmas Eve
President's Day	Columbus Day	Christmas Day

The governor may close state offices for extraordinary events. DCLS will attempt to continue usual operations during inclement weather events but cannot guarantee delivery receipt.

Receiving Test Results

Results are mailed to CBO that submitted the specimen as well as faxed to the local health department. Within 48 hours of receiving a positive laboratory result, the CBO should contact the patient and link them to treatment.

Self-Collected Rectal Swab – processed by LabCorp

Studies have shown that the CT/GC NAAT is acceptable for testing rectal swab specimens. NAAT testing represents a significant advancement in CT/GC screening as previously culture, a test with comparatively poor sensitivity, was required to diagnose. FDA approval for this test is limited to genital specimens; however, LabCorp has validated use of the test for extragenital specimens. Symptoms of rectal CT/GC are nonspecific and often silent; in fact, 85% of rectal CT/GC infections are asymptomatic in men who have sex with men (MSM). Self-collected specimens increase the uptake of testing among high-risk clients and offer high acceptance among MSM; self-collection can eliminate access barriers such as stigma, shame, negative interactions with service providers, and concerns about privacy and confidentiality.

Eligibility

Clients who provide a swab sample for rectal CT/GC screening must:

- Be male;
- Have had receptive anal intercourse within the past year, regardless of condom use; and
- Have not had a positive lab test or been treated for CT or GC in past 4 weeks.

Collection Procedures and Handling

- Have client complete the Community Based Testing Assessment Form (at a minimum last name and date of birth are required to link test results) or a NovaSalud-specific form that collects the same information.
- Obtain a release of information from clients acknowledging that they were informed that test results are reported directly to the Alexandria Health Department (all test results will be reported to Alexandria Health Department regardless of client residence).
- Affix a white sticker label to the specimen collection tube with the following information:
    - Name (must be an exact match to the lab requisition form)
    - Date of birth
    - Date of specimen collection
    - Specimen type (rectal) ;
    - LabCorp test number (188672);
    - Additional patient identifier, if available (chart number, client ID, etc.)
    - Do not cover the expiration date on the specimen collection tube with the white sticker label.
- Review the collection process with the client and instruct them to collect the rectal specimen, put the swab inside the specimen collection tube, align score line with the top edge of the tube, carefully break the swab shaft, seal the tube, and put the sealed tube inside the biohazard specimen bag.
- Visually inspect the swab to assure there is evidence of use, ensure the swab is not contaminated with significant fecal matter, and ensure the lid is tight on the specimen collection tube to prevent spillage.
- Complete all fields of the lab requisition form (including race/ethnicity) and place in the side pouch of the individual biohazard specimen bag separate from the specimen tube to keep it dry.
- Collected specimens in the specimen collection tube can be stored at room temperature (2°C to 27°C) for up to 30 days (send as soon as possible; do not hold specimens unnecessarily).

Submission Issues that Delay Testing or Prompt Rejections from LabCorp

Specimens may be rejected for the following reasons:

1. Missing or inconsistent patient name; patient name on the specimen collection tube label and the lab requisition form must be consistent. Use printed specimen tube labels whenever possible and put identical labels on all locations.
2. Incorrect or missing specimen source on the specimen collection tube label and/or the lab requisition form.
3. Missing or inconsistent collection date listed on the specimen collection tube label and/or the lab requisition form.
4. Missing indication of "requested test" on the lab requisition form.
5. Use of whiteout on specimen tube label or lab requisition form. Mistakes must be corrected by marking a line and rewriting the correct information above or beside it. Any evidence of whiteout will prompt rejection.
6. Missing submitter information on the lab requisition form. Indication of the location that submitted the specimen is necessary for receipt of results.
7. Missing or broken foil top of specimen tube; the foil must be intact to preserve the sample integrity.

LabCorp Courier

LabCorp's courier services pick up specimens 365 days a year.

Receiving Test Results

Alexandria Health Department Rainbow Tuesdays Clinic will contact clients who have a positive test result and arrange for patient to come for treatment. Only patients testing positive will be contacted to inform them of their test results. If clients would like confirmation of their negative test result, the client can contact the Alexandria Health Department Clinic at 703-746-4986.

Attachment A – Community Based Testing Assessment Form

Community-Based Testing Assessment Form Today's date: _____/_____/_____

Last Name: _____ Date of Birth: _____/_____/_____

City or County of Residence: _____ State: _____ Zip: _____

Gender: ☐ Male ☐ Female ☐ Transgender (Male to Female) ☐ Transgender (Female to Male)

Race:	☐ White	☐ Pacific Islander/Hawaiian	☐ Asian
	☐ Black	☐ American Indian/Alaska Native	☐ Other _____

Ethnicity: ☐ Hispanic or Latino ☐ Non-Hispanic

Sexual health history in past 12 months (Check all that apply):	☐ Sex with male	☐ More than 1 sex partner	☐ HIV positive
	☐ Sex with female	☐ Chlamydia or gonorrhea diagnosis	☐ Jail/prison
	☐ Injection drug use	☐ Sex with someone who had syphilis	☐ Pregnancy
	☐ Illicit drug use	☐ Exchanged sex for money or drugs	
	☐ Met sex partner through internet or mobile app		
	☐ Sex with anyone you would not be able to contact again		

Symptoms in past 12 months (Check all that apply):	☐ Sore(s) in mouth/lips	☐ Condyloma lata (wart-like lesions on genitals)	
	☐ Generalized body rash	☐ Palmar/plantar rash (hands/ bottoms of feet)	
	☐ Genital sore/ lesion	☐ Sudden hair loss	☐ Swollen lymph nodes (groin)

Have you ever been diagnosed with syphilis?	☐ Yes (If yes, you are not a candidate for the rapid syphilis test)	☐ No	☐ Not Sure

For Office Use Only:

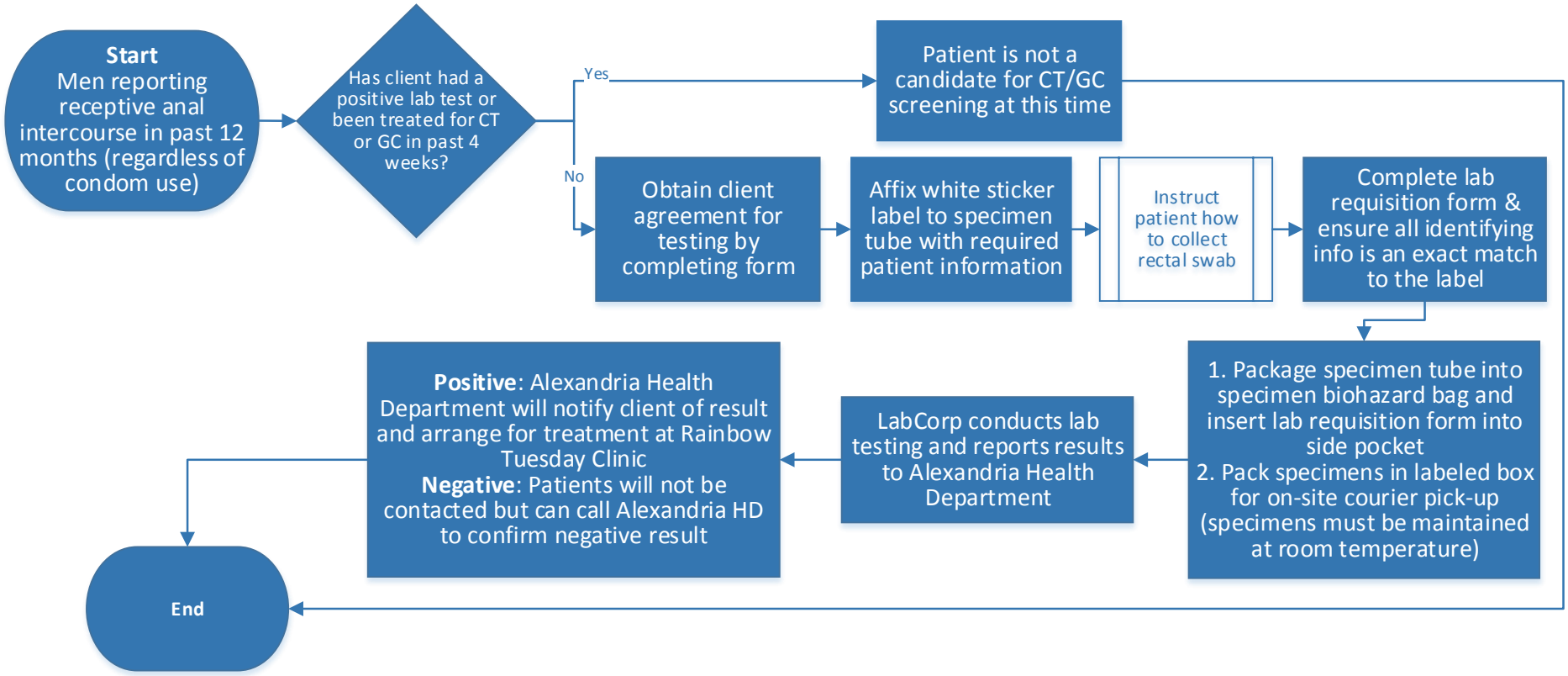
Rapid Syphilis Test results:	☐ Positive (complete Epi-1 & attach)	☐ Negative	☐ Invalid
Rectal CT/GC:	☐ Specimen collected (MSM only)		

Site ID* of agency completing assessment: _____
*same ID used for HIV Testing

Mail or fax assessment forms to:
(804) 864-7970
Attention: DDP SODA

Virginia Department of Health
Division of Disease Prevention, 2nd floor
109 Governor Street
Richmond, VA 23219

Attachment B – CT/GC Self-Collected Rectal Screening Work Flow



Alexandria Health Department: patients can call 703-746-4986 to confirm negative test result
DDP Contract Monitor Contact Information: Fax: 804-864-7970; Email: emily.cothran@vdh.virginia.gov
CT: chlamydia; **GC:** gonorrhea
Forms: submit client forms by the 10th of the following month.
Specimen tube label: must contain name (must be an exact match to the lab requisition form); date of birth; date of specimen collection; specimen type (rectal; LabCorp test 188672); additional patient identifier, if desired (chart number, client ID, etc.). Note: *Do not cover the expiration date on the specimen tube with the white sticker label*.
Supplies: Order test kits & lab requisition forms from Contract Monitor

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Attachment C – Self Collection of Rectal Swab

Self-Collection of Rectal Swab

ATTENTION: Read ALL instructions before you begin!

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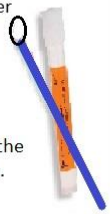
STEP 1

Wash your hands thoroughly.

STEP 2

Open the wrapper and remove the swab with the blue handle.



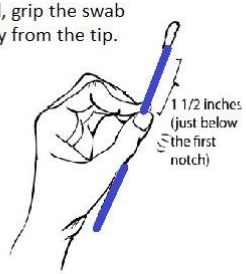
Do NOT touch the tip of the swab.

STEP 3

Pull underwear down or off. Squat down, or lift one leg up on a ledge, toilet, or chair.

STEP 4

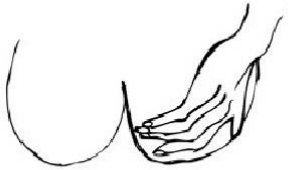
With one hand, grip the swab 1.5 inches away from the tip.

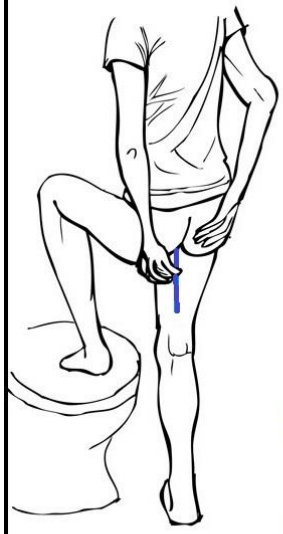


Do NOT use any kind of lubricant (soap, saliva, etc) on either the swab or your body.

STEP 5

Use your other hand to lift one cheek for easy access to the rectum.





STEP 6

Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.

STEP 7

Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there for stability.

STEP 8

Gently turn the swab in circles for approximately 30 seconds.

STEP 9

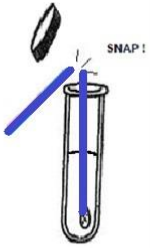
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

STEP 10

Uncap tube and keep upright - do not pour out the clear liquid. Place the swab into the tube.

STEP 11

Align the score line with the top edge of the tube and carefully break the shaft of the swab.

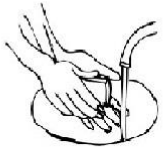


STEP 12

Swab will drop to the bottom of the tube. Screw cap on tightly so it doesn't leak.

STEP 13

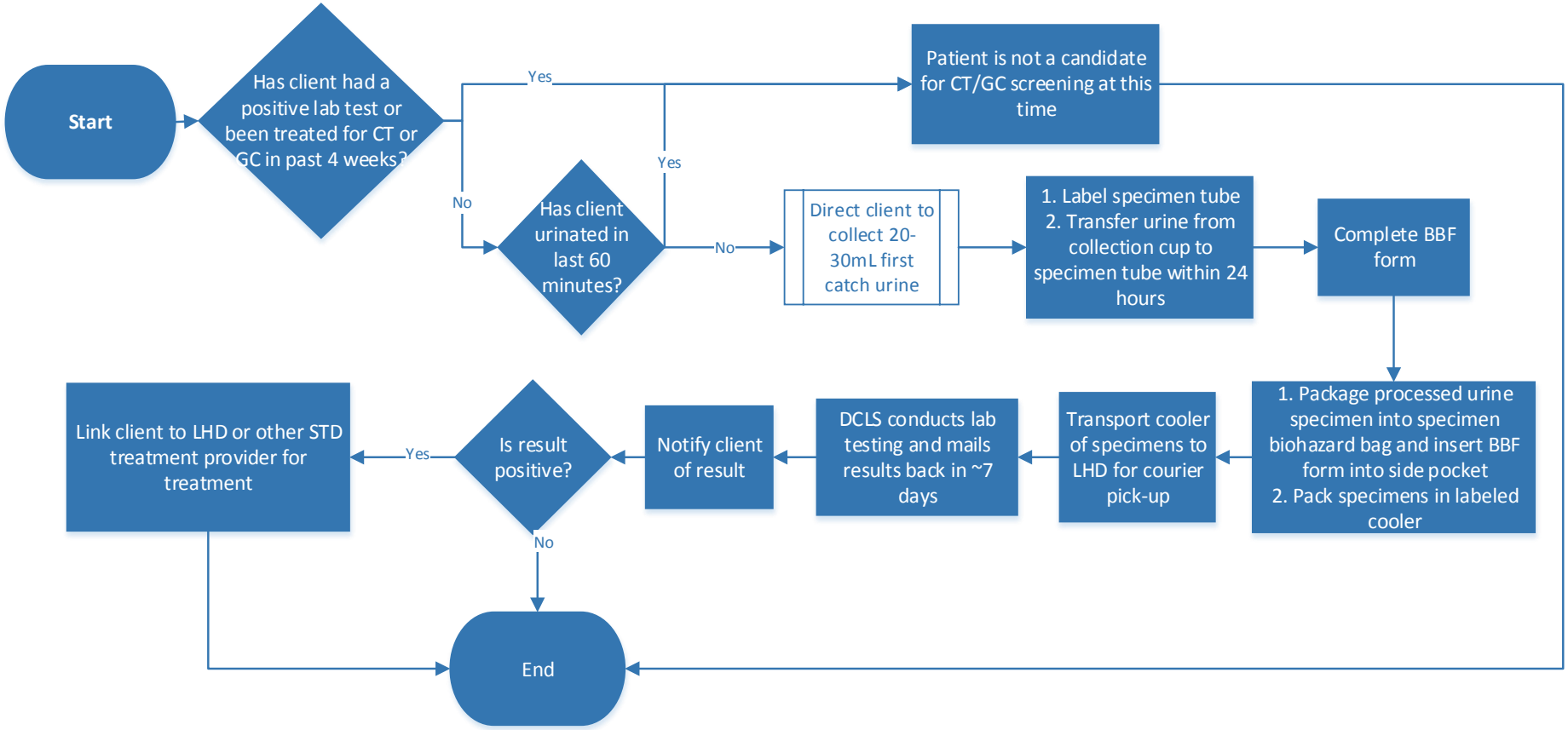
Wash your hands thoroughly.



STEP 14

Return the tube to your health care provider.

Attachment D – CT/GC Urine Screening Work Flow



Order test kits & forms from Contract Monitor
Order urine collection cups, specimen biohazard bags, etc. from medical supplier

Blood & Body Fluid (BBF) form: DCLS lab requisition form that contains patient info and requested test
Epi-1: includes data on patient demographics, diagnosis, laboratory confirmation, reporting facility, and treatment. Print from: http://www.vdh.virginia.gov/Epidemiology/documents/pdf/epi1.pdf. CBO sends copy to LHD; LHD sends copy to DDP
DCLS: Division of Consolidated Laboratory Services
Contract Monitor Contact Information: Fax: 804-864-7970; emily.cothran@vdh.virginia.gov

DDP: Division of Disease Prevention, a unit within VDH's Office of Epidemiology (http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/); mailing address: Virginia Department of Health DDP – 2nd floor; 109 Governor Street Richmond, VA 23219); fax 804-864-7970
LHD: local health department
Specimen tube label: must contain **n**ame (must be an exact match to the lab requisition form); date of birth; date of specimen collection; specimen type (urine); additional patient identifier, if desired (chart number, client ID, etc.). Note: *Do not cover the expiration date or fill area on the specimen tube with the white sticker label.*

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Attachment E – Self Collection of Vaginal Swab

Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!

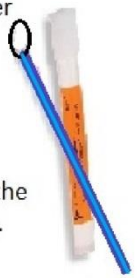
VDH VIRGINIA DEPARTMENT OF HEALTH

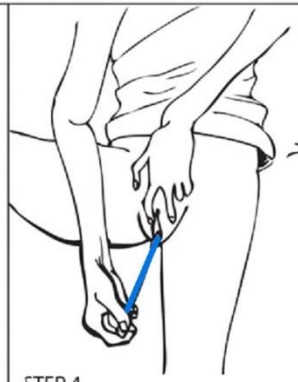
STEP 1
Wash your hands thoroughly.

STEP 2
Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina- such as sitting on the toilet, or standing with one foot on a chair, or any position that you would use to insert a tampon.

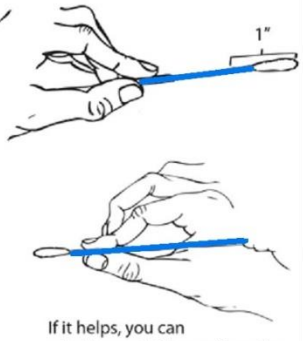
STEP 3
Open the wrapper and remove the swab with the blue handle.

Do NOT touch the tip of the swab.

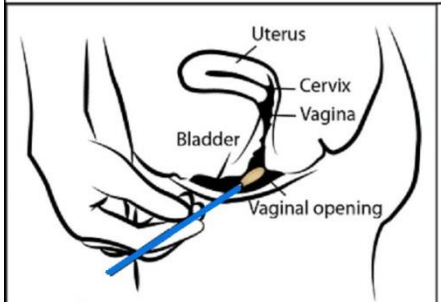




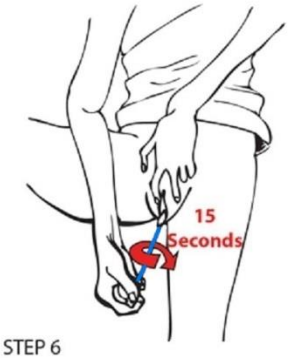
STEP 4
Insert the white tip of the swab about one inch inside the opening of your vagina.

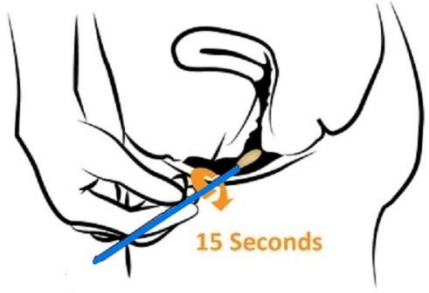


If it helps, you can grip the swab 1" away from the end of the soft tip, so your fingers will touch your body when the swab is in far enough.



STEP 5
Rotate the swab for 15 seconds, making sure that the swab touches the walls of your vagina so that moisture is absorbed into the swab.





STEP 6
Remove the swab from your vagina. Don't let the tip of the swab touch anything else.

STEP 7
Uncap tube and keep upright do not pour out the clear liquid. Place the swab into the tube.

STEP 8
Align the score line with the top edge of the tube and carefully break the shaft of the swab.

STEP 9
Swab will drop to the bottom of the tube. Screw cap on tightly so it doesn't leak.

STEP 10
Wash your hands thoroughly.

STEP 11
Return the tube to your health care provider.